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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/788,866	02/27/2004	Fred J. Molz	4002-3434 / PC834.00	7218
30565 7590 12/03/2008 WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP 111 MONUMENT CIRCLE, SUITE 3700 INDIANAPOLIS, IN 46204-5137				
EXAMINER RAMANA, ANURADHA				
ART UNIT 3775		PAPER NUMBER		
MAIL DATE 12/03/2008		DELIVERY MODE PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/788,866

Applicant(s)

MOLZ ET AL.

Examiner

Anu Ramana

Art Unit

3775

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37, 59 and 60 is/are pending in the application.
- 4a) Of the above claim(s) 8, 12 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-11, 13-16, 18-37, 59 and 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 20, 2007 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 9-11, 13-16, and 18-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the recitation, "optionally, a second sheath.....encasing the first sheath" renders the claim vague and indefinite. Is the second sheath part of the claimed invention or not?

For examination purposes, a second sheath is not considered to be part of the invention of claim 1.

In claim 9, the recitation "the plurality of fibers are braided to provide the first sheath" renders the claim vague and indefinite since it is unclear what structure is being claimed. Are the fibers forming the cord used to form the sheath?

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 10, 19-26, and 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Dunn et al. (US 4,731,084).

Dunn et al. disclose a prosthetic ligament or "surgical tether" including: a cord 30; a first sheath 20, encasing the cord, the sheath made of a plurality of fibers; a second outer sheath 40; and a radiopaque element or barium sulfate in the cord (col. 3, lines 47-68, col. 4, and col. 5, lines 1-46).

Regarding the limitation "providing an abrasion resistant coating to the cord," it is noted that since the sheath covers the cord it provides an abrasion resistant coating.

Claims 1-2, 4, 6, 9-10, 19-31, and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Kapadia et al. (US 4,883,486).

Kapadia et al. disclose a prosthetic ligament or "surgical tether" including: a core 17 of high tenacity polyester (an elastomeric material) fibers; a sheath of braided strands of PTFE, an elastomeric material, attached to the core by stitching (or "means for attaching"); and a radiopaque monofilament 19 containing barium sulfate in core 17 (Figs. 1 and 3, col. 2, lines 34-68, col. 3, lines 1-29 and lines 53-68, col. 4 and col. 5, lines 1-18).

Regarding claim 27, Kapadia et al. disclose that the core strands and the sheath may be coated with soluble collagen, a biodegradable material.

Claims 1-4, 6-7, 9, 11, 13-16, 18-23, 28-32, and 33-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Muller et al. (US 4,345,339).

Muller et al. disclose a biologically implantable member or "surgical tether" 1 including: a core 2 including a metallic wire or radiopaque element and a tube 4 with braided fibers; an inner sheath of a ring of outer filaments including a metallic wire or radiopaque element; and an outer braided sheath or cover (5, 9 or 11) (Figs. 1-6, col. 3, lines 14-68 and col. 4).

Using an alternate interpretation, claims 59 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Muller et al. (US 4,345,339).

Muller et al. disclose a biologically implantable member or "surgical tether" 1 including: a core defined by sheath 11 including multiple metallic filaments; a first sheath 5 with braided fibers, forming an abrasion resistant coating; and a metallic wire or radiopaque fiber 6, between the core and the sheath, the fiber contacting the sheath and the core (Fig. 2, col. 3, lines 14-68 and col. 4).

Regarding the limitation, "2000 N or more," it is noted that the core has multiple metallic filaments, with diameters ranging from 0.1 to 1 mm, that jointly provide a tensile strength of 2000 N or more. Andrews et al. (US 4,631,082) clearly show superalloys (CoNiCrMoTi alloys) to have an ultimate tensile strength of at least 250 k.s.i. or (1725 Newtons/square m) (col. 2, lines 18-45).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 13, 14, 59 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kapadia et al. (US 4,883,486).

Regarding claim 13, Kapadia et al. disclose the claimed invention except for a plurality of radiopaque elements. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided more than one radiopaque element, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding claim 59, Kapadia et al. disclose that the packing density of their ligament, defined by the number of core strands to the cross-sectional area of the sheath lumen is a matter of choice, based on the tensile strength desired for a specific application (col. 6, lines 3-25).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have adjusted the packing density so that the tensile strength of the cord is 2000 N or more, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding claims 11 and 60, Kapadia et al. discloses the claimed invention except for a radiopaque element in the sheath or a radiopaque element placed between the sheath and the cord. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a radiopaque element in the sheath instead of the core since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 7.

Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kapadia et al. (US 4,883,486) in view of Schmitt et al. (US 5,697,970).

Kapadia et al. disclose all elements of the claimed invention except for the use of a radiopaque marker such as a biocompatible metallic fiber.

It is well known in the art to use radiopaque markers that are metallic fibers, such as stainless steel or titanium, or polymeric fibers filled with radiopaque particles as evidenced by Schmitt et al. (col. 5, lines 12-15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted a metallic fiber as, for example, taught by the Schmitt et al. reference for the polymeric fiber filled with radiopaque particles of the Kapadia et al. device, wherein so doing would amount to mere substitution of one functionally equivalent radiopaque marker for another within the same art and the selection of any of these markers would work equally well in the Kapadia et al. device.

Claims 15-16, 18 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kapadia et al. (US 4,883,486) in view of Poirier et al. (US 2,737,075).

Kapadia et al. disclose a prosthetic ligament or "surgical tether" including: a core 17 of high tenacity polyester fibers and an attached sheath of braided strands of PFTE; and a radiopaque monofilament 19 in core 17 (Figs. 1 and 3, col. 2, lines 34-68, col. 3, lines 1-29 and lines 53-68, col. 4 and col. 5, lines 1-18).

Kapadia et al. teach all elements of the claimed invention except for multiple outer sheaths or casings.

Poirier et al. teach a cord structure including a core and a plurality of braided casings or sheaths wherein the number of casings or sheaths can be varied to provide a desired overall size and for flexibility and wherein the multiple casings are loosely disposed on the core and adapted to interlock under tension (col. 1, lines 63-72 and col. 2, lines 1-25).

Therefore, it would have been recognized by one of ordinary skill in the art that applying the known technique of providing a plurality of braided casings or sheaths, as taught by Poirier et al., in the Kapadia et al. ligament would have yielded predictable results, i.e., to obtain a desired size with improved flexibility and resistance to tension.

Claims 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al. (US 4,345,339).

Muller et al. disclose the filaments to be coated with a suitable plastic but are silent about the type of plastic. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used a biocompatible plastic, such

as polypropylene or polyethylene, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

Applicant's arguments have been fully considered but are not persuasive with respect to the rejections under 35 US 102(b) over Dunn et al. as discussed in this office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
November 28, 2008

/Anu Ramana/
Primary Examiner, Art Unit 3775